REMARKS

Upon entry of this amendment, claims 1, 6-10, 16-17 and 29-30 are currently pending in the present application, with claims 14, 15, 19-28 and 31-47 having been provisionally withdrawn by the Examiner as being directed to a non-elected species. Claim 1 is an independent claim drawn to an extended or controlled release product with the remaining claims under consideration depending therefrom and adding further limitations. Claims 2-5 and 11-13 were previously canceled without prejudice or disclaimer to the subject matter contained therein. Claim 1 has been amended to better define the inventive subject matter. No new matter within the meaning of 35 USC 132 is added by the amendments to the claims.

Claims 1, 6-10, 16-18, 29 and 30 stand rejected under 35 U.S.C. §103(a) as being obvious over Faour (U.S. Patent No. 6,352,721).

These amendments and remarks are presented in the expectation that they place this application in condition for allowance. Accordingly, entry of the remarks is respectfully requested.

Rejection of Claims 1, 6-10, 16-18, 29 and 30

under 35 U.S.C 103(a)

Claims 1, 6-10, 16-18, 29 and 30 stand rejected under 35

U.S.C. §103(a) as being obvious over Faour (U.S. Patent No. 6,352,721) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

Applicant respectfully submits that the reference of record, the Krishnamurthy patent, does not teach or suggest Applicants' inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference that would lead one of ordinary skill in the art to modify the reference to arrive at the subject of the amended claims with any expectation of success at the time the invention was made.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and

(3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

A. The present inventive subject matter

Independent claim 1 is drawn to an extended or controlled release encapsulated product, comprising: at least one active ingredient comprising a psychotropic; at least one erodible polymer selected from the group consisting of sodium carboxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, carboxymethyl cellulose ethyl cellulose, cellulose acetate methyl carbamate, methylcarbamate, polydiethylaminomethylstyrene, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose alkanylate, monoalkenytes, dialkenytes, trialkenytes,

mono-, di- and tri-arolyates, cellulose trivalerate, cellulose trioctanoate, cellulose tripropionate, cellulose diesters, cellulose disuccinate, cellulose acetate valerate, cellulose acetaldehyde, dimethylcellulose acetate, cellulose dimethylaminoacetate, semipermeable sulfonated polystyrenes, semipermeable styrenes, and mixtures thereof; and, at least one lubricating material. The product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.

The remaining claims depend from claim 1, or from a claim that depends from claim 1, and therefore necessarily contain all of the limitations found therein.

B. The prior art

The Faour patent (U.S. Patent No. 6,352,721) discloses delivery devices capable of delivering one or more active substances by diffusion through plural micropores in the membrane or by osmotic pumping though one or more preformed passageways in the membrane. The device has an about centrally located expandable core completely surrounded by an active substance-containing layer, which is completely surrounded by a membrane. The device is capable of delivering insoluble, slightly soluble, sparingly soluble and very soluble actives.

C. The differences between the claimed subject matter and the prior art

The differences between applicant's inventive subject matter and the cited reference is apparent from their independent and distinct disclosures and claims. Claim 1 (and the claims which depend therefrom) claim an extended or controlled release encapsulated product, comprising at least one active ingredient comprising a psychotropic, at least one erodible polymer selected from a group consisting of a number of different erodible polymers, and at least one lubricating material. The product is in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.

Applicants respectfully submit that the Faour patent does not disclose the claimed invention, nor would it be obvious to modify the Faour patent to attempt to achieve the claimed invention. In fact, Applicants respectfully submit that the Faour patent is totally irrelevant to the claimed invention in that one of ordinary skill in the art would not be lead by the Faour patent, which includes membranes, osmotic pumping and passageways, to the presently claimed invention, which contains none of those

characteristics.

Applicants respectfully submit that, in particular, the Faour patent does not disclose the important feature of the **size** of the dosage product. As Applicants have indicated previously, the size of the caplet aids in providing a controlled or extended release product with high levels of active ingredients and helps produce a product with uniform active ingredient content throughout. The size of the caplet also helps withstand mechanical pressure both in the processing of the caplet and in the chewing of the product in the mouth so that the active ingredients are released in the stomach of the consumer. In addition, the smaller size of the product allowed for better controlled release of the active ingredients. The smaller size results in a different erosion pattern, yet the release of the active ingredient is better controlled through the small size of the delivery medium. Thus, **the size of the caplet is an important feature of the present inventive subject matter**.

In support of this position, Applicant respectfully submits herewith comparative test data showing the desired delivery of a pharmaceutical from the claimed caplets in comparison with a larger tablet and a capsule filled with granules. Applicant prepared an in vitro dissolution test to indicate the importance of the size of the caplets on the desired dissolution profile. In particular,

Applicant prepared a composition containing (all percentages herein are given as weight percent) 61.88% venlafaxine Hcl, 16.21% glyceryl behenate, 16.21% microcrystalline cellulose, 4.38% ethyl cellulose, 0.88% magnesium stearate, and 0.88% purified talc. The ingredients were granulated and dried, then coated with a solution containing 5.00% ethyl cellulose, 0.50% triethyl citrate, and 94.50% isopropyl alcohol. The composition was then divided into three portions. A first portion was loaded (as granules) into a capsule. A second portion was tableted to a size of 11 mm, while the third portion was compressed into caplets having a size of 3 mm. The three products were then tested for their dissolution profile in 0.1N Hcl using paddles at 100 rpm with a volume of 1000 ml. The results of the dissolution are shown in the attached chart.

As can be seen from the chart, Applicant has found that caplets having the claimed size exhibit a more desired release profile, having a zero order. Surprisingly, the larger tablets and the capsules containing the granules exhibited release profiles that were very similar, and were not of zero order. Thus, the data shows that the smaller size of the caplets provides greater control over the release of the active ingredient.

Applicants respectfully submit that the Faour patent is silent

with respect to these features and there is no motivation or teaching within the patent to modify it in an attempt to achieve the present subject matter. As is indicated above, the patent is concerned with a dosage form that involves a membrane, osmotic pumping and/or passageways for release of the active ingredient, and is not concerned about the size of the dosage form.

Since the teachings of the Faour patent is deficient in disclosing each claimed limitation, **including the erodible polymers and the size of the caplets**, Applicants respectfully submit that the Examiner has failed to prove a *prima facie* case of obviousness, which requires that the prior art references teach or suggest all of the claimed limitations. It is clear that the prior art reference cited by the Examiner fails to accomplish this and there is no motivation to modify the reference, and thus the claims are not obvious over the references. Applicant, therefore, respectfully request reconsideration and withdrawal of the alternative obviousness rejection.

Accordingly, Applicant respectfully submits that the present inventive subject matter, as claimed in the rejected claims, is not rendered obvious by the Faour patent. Applicant request reconsideration and withdrawal of these rejections.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that the present claims are patentable over the prior art of record in this case and requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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